IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	)	
	)	
Wm. A. KNAUS & Richard D. MARKS	)	**Group Art Unit: 3626**
	)	
Application No: 09/822,261	)	**Examiner: Lena A. Najarian**
	)	
Filed: March 26, 2001	)	
	)	

Title: BROADBAND COMPUTER-BASED NETWORKED SYSTEMS FOR CONTROL AND MANAGEMENT OF MEDICAL RECORDS

MAIL STOP = APPEAL BRIEF - PATENTS

Commissioner for Patents
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANT'S BRIEF ON APPEAL

Sir:

This Appeal is from the Examiner's Final Rejection of claims 1-29, 46-62, 64-71 and 73-75, and the Notice of Panel Decision from Pre-Appeal Brief Review of these same claims.

REAL PARTY IN INTEREST

The real party in interest is Patient Command, Inc., a Delaware corporation with its place of business in McLean, Virginia.

RELATED APPEALS AND INTERFERENCES

To the best of the undersigned's knowledge, there is one other related appeal pending within the meaning of 37 CFR 1.192(c). An Appeal Brief was filed on October 12, 2006, with respect to United States Patent Application No. 09/816,152, which is the parent of the instant application. To the best of the undersigned's knowledge, there is no other related Appeal or Interference within the meaning of 37 CFR 1.192(c).

STATUS OF CLAIMS

Claims 1-59 were originally filed with this application. In a Preliminary Amendment filed and dated July 7, 2004, Appellant amended claims 1, 8, 9, 15, 20, 25, 26, 30, 31, 40, 46, 51-53, 54, 56 and 58. In an Amendment filed and dated February 25, 2004, Appellant canceled claims 30-45, amended claims 1 and 46, and added new claims 60-75. In an Amendment filed and dated April 20, 2005, Appellant canceled claims 63 and 72, and amended claims 1, 10, 11, 20, 25, 65, 68 and 73. In an Amendment filed and dated May 12, 2005, Appellant amended claims 1, 10, 11, 19-21, 23, 25-28, 46, 54, 55, 59, 61, 63-66, 68, 70-73 and 75. In an Amendment filed and dated August 26, 2005, Appellant amended claims 1, 21, 46 and 65. In an Amendment filed and dated June 6, 2006, Appellant amended claims 1 and 65. All these amendments have been entered by the Examiner.

Claims 1-29, 46-62, 64-71 and 73-75 are currently pending in the application, and these same claims are before the Board. A copy of these claims is appended hereto.

STATUS OF AMENDMENTS

Subsequent to the final Office Action from which this appeal is based, Appellant canceled claims 62 and 73, and amended claims 1, 10, 11, 20, 25, 65, 68 and 73. In an Advisory Action mail dated June 26, 2006, the Examiner checked box 7(b), indicating that, for purposes of this appeal and further prosecution, all amendments would be entered.

SUMMARY OF CLAIMED SUBJECT MATTER

Appellant's claimed invention is directed to a broad-band, computer-based, networked system of medical health records (specification at page 9, lines 10-12). The system comprises a collection of patient-based, as contrasted with hospital-based or institutional-based, electronic medical records that are encrypted, or secured when collected, accessed, input, viewed, integrated and/or transmitted (*Id.* at page 7, lines 4-5 and 16-17, and page 14, lines 21-23). The electronic medical records are obtained from a plurality of sources, such as hospitals, doctors and clinicians, to name a few (*Id.* at page 13, lines 20-21 and page 18, lines 25-27). At least one medical record of the collection possesses the characteristic of non-repudiation, such that the medical information contained is as good or better than exists at the source from which the medical record was obtained (*Id.* at page 17, lines 14-17 and page 21, lines 20-24). The

electronic medical record may be transmitted in whole or in part, and may be supplemented with additional information (*Id.* at page 23, lines 9-10 and lines 15-16).

In an embodiment, a broad-band, computer-based networked system has a collection of patient-based electronic medical records of a plurality of persons, and at least one of which is encrypted or secured when collected, accessed, inputted, viewed, integrated or transmitted (*Id.* at page 10, lines 1-6, page 18, lines 1-5). The medical records are obtained and electronically compiled from a plurality of sources and one or more medical records of the collection possess a characteristic of non-repudiation, such that medical information contained within the medical records is verified as to accuracy and certified for accuracy (*Id.* at page 17, lines 14-17 and page 21, lines 20-28). The medical record of a person is transmitted in whole or in part only to that person and others authorized by that person (*Id.* at page 15, lines 1-3 and page 23, lines 9-14). Each medical record is supplemented with additional information, and additional medical records for additional persons are added to the collection with a secure access for allowing each person to access only their own medical record and at least another secure access for allowing the others authorized to access only that person's medical record (*Id.* at page 23, lines 15-16, page 15, lines 15-16, page 7, lines 13-14, page 13, lines 4-6).

In another embodiment a broad-band, computer-based networked system for individual control and management of electronic medical records has a plurality of medical records representing a plurality of persons, and the medical information of at least one medical record of the plurality has been vetted, such that the medical information of the at least one medical record is better than exists at a source site from which the medical record was obtained and thereby is not subject to repudiation (*Id.* at page 9, lines 10-12, page 17, lines 22- 25 and lines 14-17, and page 21, lines 20-28).

In still another embodiment, a computer system for management of patient-based medical records that contain medical information and are not subject to repudiation has a database of medical records pertaining to one or more subjects, a receiver for receiving the medical information pertaining to the medical records from one or more senders, a process for verifying that the medical information received is accurate and correct by at least vetting the medical information, a process for authorizing the senders and the additional receivers according to a set of rules that is designated by the subjects, and a transmitter for transmitting at least a portion of the medical records to one or more additional receivers and certifying that the portion transmitted

is accurate (*Id.* at page 17, lines 22-25 and lines 14-17, page 21, lines 20-28, page 13, lines 4-6 and page 15, lines 1-3).

Still another embodiment is a networked system having a collection of patient-based electronic medical records containing medical information (*Id.* at page 18, lines 7-13 and page 24, lines 22-23). The medical records are obtained and electronically compiled from a plurality of sources and the medical information contained within one or more medical records is verified as to accuracy and certified as to accuracy, and thereby possesses the characteristic of non-repudiation (*Id.* at page 13, lines 20-21, page 18, lines 25-28, page 17, lines 14-17 and page 21, lines 20-28) The medical records are transmitted in an encrypted fashion in whole or in part only to that person and others authorized by that person (*Id.* at page 21, lines 1-5). Each medical record is supplemented with additional information and additional medical records for additional persons are added to the collection (*Id.* at page 23, lines 15-16 and page 24, lines 22-23). Also included is a capability of having multiple secure accesses for a person and others authorized by the person to access only their own medical record (*Id.* at page 17, lines 25-29).

In one embodiment, medical records of the collection can be primary for treatment of the patient to whom the record pertains (*Id.* at page 13, lines 8-13). In another embodiment, the medical records may be accessed only by the patient or individuals authorized by the patient (*Id.* at page 17, lines 25-29). The collection complies with federal and state standards of medical record privacy and security such as the Health Insurance Portability and Accountability Act of 1996 (*Id.* at page 13, lines 21-23).

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

At issue is whether claims 1-29, 46-62, 64-71 and 73-75, are patentable over certain alleged prior art references. Also at issue is whether Appellant's Affidavit is sufficient to remove two prior art references under 37 C.F.R. § 1.131 (Snowden and/or Malik), and whether claim 20 was properly examined.

GROUPING OF CLAIMS

The claims do not stand or fall together, but are divided into four groups. The first group includes those claims that contain elements that are not disclosed in the cited prior art. The second group includes those claims that stand rejected in view of Snowden and other prior art

references. The third group represents those claims that stand rejected in view of Malik and certain other prior art references. The fourth group includes one claim that Appellant respectfully asserts has not been properly examined.

Group I

Claims 1-11, 18-26, 29, 46-47 and 51-75 stand rejected over Snowden (US 2002/0026332 A1; "Snowden") in view of Shepard (US 6,026,363). These claims include the elements of "certification" and "non-repudiation," which Appellant respectfully asserts are not disclosed or suggested in either prior art reference.

Group II

Claims 1-29, 46-62, 64-71 and 73-75 stand rejected as allegedly obvious over Snowden or Snowden in combination with other references. Appellant respectfully asserts that Appellant's Affidavit effectively removes Snowden as prior art.

Group III

Claims 13-15, 27-28 and 48-50 stand rejected as allegedly obvious over Snowden in combination with Malik (US 2001/0037219 A1; "Malik"). Appellant respectfully asserts that Appellant's Affidavit effectively removes Malik as prior art.

Group IV

Claim 20 stands rejected, under 35 U.S.C. § 103(a) in view of Snowden or Snowden in combination with other references. Appellant respectfully asserts that at least one claim element is not suggested in the combination, and also that the Examiner failed to demonstrate that this element is suggested in the cited prior art.

ARGUMENT

Appellant received a non-final Office Action, mail dated August 1, 2005, wherein Appellant's claims stood rejected, under 35 U.S.C. § 103(a), as allegedly obvious over Snowden (U.S. Patent Application No. 2002/0026332; "Snowden") in view of Shepard (U.S. Patent No.

6,026,363), and further in view of Baker (PCASSO), Malik (US Patent Application No. 2001/0037219; "Malik") or Shear (U.S. Patent No. 4,827,508).

To establish *prima facie* obviousness, the Examiner must show in the prior art some suggestion or motivation to make the claimed invention, a reasonable expectation for success in doing so, and a teaching or suggestion of each claim element (*see, e.g., In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347 (Fed. Cir. 1992); *In re Merck & Co., Inc.,* 800 F.2d 1091 (Fed. Cir. 1986); *In re Royka,* 490 F.2d 981 (CCPA 1974)). Most inventions arise from a combination of old elements, and each element may often be found in the prior art (*In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998)). However, mere identification in the prior art of each element is insufficient to defeat the patentability of the combined subject matter as a whole (*Id.* at 1355, 1357). Rather, to establish a *prima facie* case of obviousness based on a combination of elements disclosed in the prior art, the Examiner must articulate the basis on which it concludes that it would have been obvious to make the claimed invention (*Id.*). In practice, this requires that the Examiner "explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious" (*Id.* at 1357-59). This entails consideration of both the "scope and content of the prior art" and "level of ordinary skill in the pertinent art" aspects of the *Graham* test. The Examiner failed in this regard.

In view of the above, Appellant respectfully asserts that the Examiner's rejection is based on an "obvious to try" standard rather than the requisite *Graham* factors. The cited art provides no indication of which parameters are critical and provides no direction as to which combination and/or modification of parameters is likely to be successful (*See e.g., In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988). Indeed, the cited art specifically teaches away from Appellant's invention. The entirety of the Examiner's prior art analysis is error, and should be rejected.

In this Office Action, the Examiner re-interpreted many elements of the claimed invention. Appellant responded, traversing each rejection and the Examiner's re-interpretations as improper and internally inconsistent. Appellant also furnished an affidavit under 37 C.F.R. § 1.131 with supporting evidence (the "Affidavit). Under M.P.E.P. § 715, the Affidavit demonstrates that, prior to both Snowden's and Malik's filing dates, the inventors had conceived and/or reduced to practice the elements of the claimed invention actually found in Snowden and Malik. Therefore, if the Examiner agreed that her re-interpretations were incorrect, the rejections

would be withdrawn. However, if the Examiner refused, the Affidavit renders the rejections moot.

The Examiner next issued a final Office Action mail dated March 2, 2006, reasserting the same rejections. No rejections were reconsidered, and the Examiner refused to modify her reinterpretation of the claims. The Examiner now asserted that Appellant's Affidavit failed to demonstrate conception and/or reduction to practice "*of the whole invention claimed or something falling within the claims*" (final Office Action, page 15), because she was unable to locate Appellant's *entire* invention in the Affidavit, and because Appellant failed to show a "nexus" between the Affidavit and the claimed invention. Because the Examiner's analysis contains material errors, including violation of the MPEP, withdrawal of the rejections is appropriate.

Analysis of the examination of the claims to date reveals:

(1) a failure to deal with each claim, and in particular claim 20;

(2) confusion between two critical sections of the Code of Federal Regulations (37 CFR §§ 1.131 and 1.132), leading to a direct, erroneous, adverse impact on the Examiner's conclusions with regard to an affidavit submitted under § 1.131; and

(3) two mutually inconsistent interpretations of the word "actual" in the § 1.131 affidavit and asserted prior art which, when carefully compared, lead inevitably to a conclusion that either the prior art is does not teach the claimed invention or, alternatively, that the § 1.1131 affidavit demonstrates the Appellant's earlier invention of "accuracy" as found in the asserted prior art.

Taken together or separately, these errors in the examination demonstrate that all rejections in the final Office Action should be withdrawn, and a Notice of Allowance promptly issued.

I. Argument with Respect to Group I Claims (claims 1-11, 18-26, 29, 46-47 and 51-75)

Errors in Examining Appellant's Claims of "Certification" and "Non-Repudiation," Particularly a Teaching Away, Show Hindsight and Violation of the MPEP, So That Rejections for Failure to Disclose the Claimed Invention and for Obviousness Must Be Withdrawn.

A. The Claim Elements of "Certification" and "Non-Repudiation," are not Disclosed in the Cited Prior Art, Leading to an Improper Rejection Because *Prima Facie* Obvious has not been Established.

The combination of the cited references fails to disclose or suggest at least "certification" and "non-repudiation." To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be suggested by the prior art (*In re Royka*, 490 F.2d 981 (CCPA 1974)). Appellant respectfully asserts that the cited references fail to disclose all the limitations of the instant claimed invention.

1) The Claim Element of "Non-Repudiation."

Nonrepudiation is positively recited as an element of Appellant's claimed invention (e.g., claims 1, 8-10, 26, 46, 63, 65, 70 and 71). In claim 1, medical information contained within medical records is verified as accurate and correct such that: "*one or more records of the collection possess a characteristic of non-repudiation.*" This element is also clear from the specification: *"Medical records that are verified as accurate attain the aspect of nonrepudiation (i.e. that the accuracy and correctness of the information [in the medical record] is as good or better than exists at the source from which the records were obtained) and may for all purposes be relied upon"* (specification, page 17, lines 14-17). This claim element is understood by those of ordinary skill in the art. Appellant is not incorporating a definition from the specification, but merely demonstrating that the specification is consistent with the context and the plain meaning of this term in the claims.

The Examiner admits that: "Snowden does not expressly disclose one or more medical records of the collection posses a characteristic of non-repudiation such that the medical information contained within said medical records is verified as to accuracy or transcription and certified for accuracy of transcription" (see non-final Office Action, page 6). Appellant interprets this statement to mean that Snowden does not disclose or suggest non-repudiation as claimed by Appellant.

2) The Claim Element of "Certification."

Certification is positively recited as an element of Appellant's claimed invention (e.g., claims 1, 11, 21-23, 63, 65, 72 and 73). In claim 1, the invention comprises a collection of medical records such that "medical information contained within said medical records is verified as to accuracy and certified for accuracy." Appellant states: "*The invention may include a form of medical record that can be completed at one of a plurality of certification levels*" (specification, page 15, lines 12-13). "*Certification levels refer to standards of verification such as, for example, 'initial' being self-certification wherein the member certifies that the record is correct, 'basic' whereby the system provider certifies that the record is complete for all information gathered ...*" (specification, page 15, lines 22-25; and claims 20, 37, 43). This claim element is understood by those of ordinary skill in the art. Appellant is not incorporating a definition from the specification, but merely demonstrating that the specification is consistent with the context and plain meaning of this term in the claims.

The Examiner admits as much: "*Snowden does not expressly disclose one or more medical records of the collection posses a characteristic of non-repudiation such that the medical information contained within said medical records is verified as to accuracy or transcription and certified for accuracy of transcription*" (see non-final Office Action, page 6). Appellant interprets this statement to mean that Snowden does not disclose or suggest Certification as claimed by Appellant.

B. The Claim Elements of "Certification" and "Non-Repudiation," are not Disclosed in the Cited Prior Art, Leading to an Improper Rejection Because *Prima Facie* Obvious has not been Established.

1) Sheppard Teaches Away From the Claimed Invention.

Shepard does not disclose or suggest at least the elements of "certification of medical records" (claims 1, 11, 21-23, 63, 65, 72 and 73) or "*nonrepudiation of medical records*" (claims 1, 8-10, 26, 46, 63, 65, 70 and 71) as these elements are claimed by Appellant, and, in fact, teaches away from Appellant's claims. The Examiner's re-interpretation of these elements by distorting claim terms to shoe-horn them into portions of Shepard is both hindsight and improper under the MPEP.

Shepard is not combinable with Snowden and would not lead one skilled in the art toward Appellant's invention. *Appellant's claimed invention is directed to patient-based records.* Shepard is directed to the conventional hospital-based or physician-office system, or, in other words, to *an institutional source-centered record system*, which leads one skilled in the art in exactly the wrong direction. As stated in Appellant's specification: "Integration of medical information is *patient-centered, not source- or physician-centered...*" (emphasis added) (specification, page 7, lines 16-17). A "teaching away," as we have here, is the strongest indication of the non-obviousness of Appellant's claimed invention.

The Shepard medical record management system is directed to physician- or a hospital-based records system. In Shepard, an advantage of the invention is that medical records are to be recorded by a "*medical history documentation system* [that] *uses a second person who functions as the recorder and is present during the physical examination and/or treatment by the first person who is the heath care professional*" (emphasis added) (*see* Shepard, column 6, lines 52-57). Shepard states that the recorder of the medical information prepares a Report Form for review by the examining physician before that physician verifies and signs the report (Shepard, column 11, lines 58-67). Only then is it considered a "Final Report Form" suitable for placing in the patient's hospital or office medical record. Thus, Shepard's records would be verified as correct only by the health care professional who conducted the examination. This is not a patient-based record system as described in the instant application, but a conventional hospital-based record system for creating original medical records.

Further, *Shepard claims no vetting or certification according to Appellant's claimed invention.* The parts of Sheppard alleged in the Office Action to disclose or suggest vetting and/or certification are column 1, lines 29-37; column 4, line 60 to column 5, line 11; column 5, lines 58-62; column 6, lines 8-13; column 8, lines 44-48; column 12, lines 8-12; column 13, line 54 to column 14, line 9; and column 14, lines 61-65. None of these sections discloses or suggests vetting or certification according to Appellant's claimed invention. All the instances noted in Shepard refer to verification of the patient's record by the physician or health care worker who is tasked by the source with creating the record in the first place. Shepard describes delegating the task of actually writing the medical record to another person employed by the source office or hospital, and yet who is not administering the care. The recorder is, for example, to be present in the room when the patient is being examined by the physician

(Shepard, column 6, lines 52-57). Once drafted by the recorder, the draft record is provided to the source-employed care-giver, most typically the examining physician, for final review before it becomes a part of the patient's institutional medical record. Thus, although Shepard may describe a system to create "original" source medical records, Shepard neither discloses nor suggests vetting or certification according to Appellant's claimed invention of a *patient-based* record. This highlights another aspect of Appellant's claimed invention, which is recited in claim 20, and clearly distinguishes the instant claims from Shepard.

With reference to instant claim 20, and in contrast to the Examiner's allegation, the information contained within Shepard's source medical records *cannot* be better than exists at the source from which the record was obtained. This is at least because the hospital, physician or health care worker is the source of the record. In other words, the Shepard system only envisions creating original medical records at the source. Therefore, Shepard cannot logically be a system of creating medical record that are "better" than exist at the source from which the records were originally obtained (*i.e.,* better than the original record).

For at least these reasons, Shepard clearly teaches away from Appellant's claimed invention, so that all rejections based on Shepard should be withdrawn for failure to disclose Appellant's claimed invention and for failure to establish a *prima facie* case of obviousness.

C. The Examiner's Mutually Exclusive Interpretations of "Accuracy" in Relation to "Certification" and "Non-Repudiation" Require, Inevitably, That Appellant's Claims Be Granted.

The Examiner created a conundrum for herself by using mutually inconsistent definitions of the word "accuracy" as the basis for (1) rejecting certain of Appellant's claims involving "certification" and "nonrepudiation" (for this purpose the Examiner defined "certification" and "nonrepudiation" as meaning "accuracy") while (2) rejecting the Appellant's § 1.131 Affidavit, swearing behind Snowden and Malik, because "accuracy" in the Affidavit did not, according to the Examiner, mean "certification" or "nonrepudiation."

First the Examiner equated "accuracy" to "certification" and "nonrepudiation" in order to reject claims 1-11, 18-26, 29, 46, 47 and 51-75 (see page 6, last line to page 7, first line in the non-final Office Action mail dated August 1, 2005), based on asserted prior art that contained the word "accuracy." Appellant then filed its § 1.131 Affidavit. That Affidavit demonstrates

unambiguously that Appellant's invention included "accuracy," as defined by the Examiner, before the date of the asserted prior art. The Examiner then changed to a different definition of "accuracy" that is mutually exclusive with her rejection based on asserted prior art. This time, the Examiner based her rejection on the ground that "accuracy" does not mean either "certification" or "nonrepudiation." Taken together, her analytical approach is devoid of logic, arbitrary and capricious, and a violation of MPEP § 706.

At this stage of the proceedings, use of either interpretation will result in a grant. This is so because either (1) the asserted prior art is irrelevant to "certification" and "nonrepudiation", or (2) if the asserted prior art is relevant to "certification" and "nonrepudiation," because "accuracy means ""certification" and "nonrepudiation," then Appellant has demonstrated in its Affidavit that its invention included "accuracy" prior to the date of the asserted prior art.

II. Argument with Respect to Group II Claims (claims 1-29, 46-62, 64-71 and 73-75)

Errors in the Examiner's Analysis of Appellant's § 1.131 Affidavit Demonstrate That the Rejections Based on Snowden Must Be Withdrawn.

The Examiner committed two clear errors in rejecting Appellant's §.1.131 Affidavit. First, she erroneously required that there be a "nexus" between the Affidavit and the claimed invention (final Office Action, p.15). Second, she erroneously required that "the whole invention claimed or something falling within the claims" be located within the Affidavit (final Office Action, page 5).

A. Requiring a Nexus is Erroneous.

As to the first error, there is no "nexus" requirement in 37 CFR §.1.131. Rather, the requirement for a "nexus" is found in §.1.132. Yet the Examiner repeatedly stated (including during the Interview of October 20, 2005) that Appellant's Affidavit fails because there is no "nexus" between the Affidavit and the instant claims (final Office Action, page 15).

Section 1.132 contains an explicit textual requirement for a "nexus" and §.1.131 does not. This textual difference precludes the Examiner from imposing a requirement for a nexus in § 1.131, as she has done. The omission of a "nexus" requirement in § 1.131, followed by the explicit textual inclusion of a "nexus" requirement in the very next section, § 1.132, in fact *requires* the Examiner to draw the negative inference that § 1.131 does not have a "nexus"

requirement, and to recognize that "nexus" cannot be read into § 1.131 by implication or any other means. This analysis follows established rules of textual interpretation. For example, in a recent case the U.S. Supreme Court analyzed two sections of a statute dealing with jurisdiction. The first provision contained a jurisdictional bar (a provision stripping courts of jurisdiction), but that bar was not contained in the second section. The Court concluded that drawing the negative inference – that the section without the jurisdictional bar could only be read as not precluding jurisdiction – was *required*:

> A like inference follows *a fortiori* from *Lindh* in this case. "If . . . Congress was reasonably concerned to ensure that [§§ 1005(e)(2) and (3)] be applied to pending cases, it should have been just as concerned about [§ 1005(e)(1)], unless it had the different intent that the latter [section] not be applied to the general run of pending cases." *Id.*, at 329, 117 S. Ct. 2059, 138 L. Ed. 2d 481. If anything, the evidence of deliberate omission is stronger here than it was in *Lindh*. In *Lindh*, the provisions to be contrasted had been drafted separately but were later "joined together and . . . considered simultaneously when the language raising the implication was inserted." *Id.*, at 330, 117 S. Ct. 2059, 138 L. Ed. 2d 481. We observed that Congress' tandem review and approval of the two sets of provisions strengthened the presumption that the relevant omission was deliberate. *Id.*, at 331, 117 S. Ct. 2059, 138 L. Ed. 2d 481; see also *Field* v. *Mans,* 516 U.S. 59, 75, 116 S. Ct. 437, 133 L. Ed. 2d 351 (1995) ("The more apparently deliberate the contrast, the stronger the inference, as applied, for example, to contrasting statutory sections originally enacted simultaneously in relevant respects"). Here, Congress not only considered the respective temporal reaches of paragraphs (1), (2), and (3) of subsection (e) together at every stage, but omitted paragraph (1) from its directive that paragraphs (2) and (3) apply to pending cases only after having *rejected* earlier proposed versions of the statute that would have included what is now paragraph (1) within the scope of that directive. Compare DTA § 1005(h)(2), 119 Stat. 2743-2744, with 151 Cong. Rec. S12655 (Nov. 10, 2005) (S. Amdt. 2515); see *id.*, at S14257-S14258 (Dec. 21, 2005) (discussing similar language proposed in both the House and the Senate). Congress' rejection of the very language that would have achieved the result the Government urges here weighs heavily against the Government's interpretation. See *Doe* v. *Chao,* 540 U.S. 614, 621-623, 124 S. Ct. 1204, 157 L. Ed. 2d 1122 (2004).
>
> . . . .
>
> Congress here expressly provided that subsections (e)(2) and (e)(3) applied to pending cases. It chose not to so provide -- after having been presented with the option -- for subsection (e)(1). The omission is an integral part of the statutory scheme that muddies whatever "plain meaning" may be discerned from blinkered study of subsection (e)(1) alone. The dissent's speculation about what Congress might have intended by the omission not only is counterfactual, but rests on both a misconstruction of the DTA and an erroneous view our precedents.

Hamdan v. Rumsfeld, 126 S. Ct. 2749, 2766 & 2769 (2006) (footnotes and internal citations omitted).

B. The Examiner's Affidavit Requirements are Erroneous.

The Examiner's second error evinces an inexplicable disregard of the clear text of MPEP § 715.02, because the Examiner's erroneously asserts that Appellant must state the entirety of its claimed invention in the Affidavit in order for her to consider the Affidavit sufficient (final Office Action, pages 5-6). This directly contravenes MPEP § 715.02, which states that Appellant *only* needs to show that the Affidavit contains *the elements of the claimed invention that are found in the supposed prior art:*

> [A]n affidavit is not insufficient merely because it does not show the identical disclosure of the reference(s) or the identical subject matter involved in the activity relied upon. *If the affidavit contains facts showing a completion of the invention commensurate with the extent of the invention as claimed is shown in the reference or activity, the affidavit or declaration is sufficient*....(Emphasis added.)

The Examiner's analytical approach to Appellant's Affidavit is contrary to the MPEP, and thus clear error. Snowden should be removed as prior art references in view of Appellant's Affidavit.

C. The Affidavit Sufficiently Describes Appellant's Invention.

In the Office Action the Examiner states that she was unable to locate "the whole invention claimed or something falling within the claims" within the Affidavit (final Office Action, page 5). Erroneously, the Examiner focuses her review on disclosures in the Affidavit that are allegedly *absent* from Appellant's claims:

> To the extent the Examiner understands the submitted materials, the Brief Background and Rationale section of the document at page 4 makes references to elements not present in any of the recited claims, namely, that the "patient would be the main repository" and `carry' the results with them to all medical encounters. (Final Office Action, pages 5-6.)

Despite the Examiner's misplaced focus, the affidavit discloses a broadband ("Internet-based"), secure repository for the "accurate" storage of patients' medical record data. This invention is wholly sufficient to swear behind Snowden.

III. Argument with Respect to Group III Claims (claims 13-15, 27-28 and 48-50)

Errors in the Examiner's Analysis of Appellant's § 1.131 Affidavit Demonstrate That the Rejections Based on Malik Must Be Withdrawn.

The Examiner committed two clear errors in rejecting Appellant's §.1.131 Affidavit. First, she erroneously required that there be a "nexus" between the Affidavit and the claimed invention (final Office Action, p.15). Second, she erroneously required that "the whole invention claimed or something falling within the claims" be located within the Affidavit (final Office Action, page 5).

A. Requiring a Nexus is Erroneous..

As to the first error, there is no "nexus" requirement in 37 CFR §.1.131. Rather, the requirement for a "nexus" is found in §.1.132. Yet the Examiner repeatedly stated (including during the Interview of October 20, 2005) that Appellant's Affidavit fails because there is no "nexus" between the Affidavit and the instant claims (final Office Action, page 15).

Section 1.132 contains an explicit textual requirement for a "nexus" and §.1.131 does not. This textual difference precludes the Examiner from imposing a requirement for a nexus in § 1.131, as she has done. The omission of a "nexus" requirement in § 1.131, followed by the explicit textual inclusion of a "nexus" requirement in the very next section, § 1.132, in fact *requires* the Examiner to draw the negative inference that § 1.131 does not have a "nexus" requirement, and to recognize that "nexus" cannot be read into § 1.131 by implication or any other means. This analysis follows established rules of textual interpretation as described above.

B. Examiner's Affidavit Requirements are Erroneous.

The Examiner's second error evinces an inexplicable disregard of the clear text of MPEP § 715.02, because the Examiner's erroneously asserts that Appellant must state the entirety of its claimed invention in the Affidavit in order for her to consider the Affidavit sufficient (final Office Action, pages 5-6). This directly contravenes MPEP § 715.02, which states that Appellant *only* needs to show that the Affidavit contains *the elements of the claimed invention that are found in the supposed prior art:*

> [A]n affidavit is not insufficient merely because it does not show the identical disclosure of the reference(s) or the identical subject matter involved in the

> activity relied upon. *If the affidavit contains facts showing a completion of the invention commensurate with the extent of the invention as claimed is shown in the reference or activity, the affidavit or declaration is sufficient*....(Emphasis added.)

The Examiner's analytical approach to Appellant's Affidavit is contrary to the MPEP, and thus clear error. Malik should be removed as prior art references in view of Appellant's Affidavit. Further, because the Examiner provided no comments regarding Malik and Appellant's Affidavit, Malik at least should be removed as a prior art reference, and all claims rejected over Malik be declared allowable.

C. The Affidavit Sufficiently Describes Appellant's Invention.

In the Office Action the Examiner states that she was unable to locate "the whole invention claimed or something falling within the claims" within the Affidavit (final Office Action, page 5). Instead of reviewing the Affidavit for the claim elements of Appellant's invention, the Examiner focused on aspects that are *absent* or minimally significant to the instant claims. For example, in the final Office Action, the Examiner stated:

> "*To the extent the Examiner understands the submitted materials, the Brief Background and Rationale section of the document at page 4 makes references to elements not present in any of the recited claims, namely, that the 'patient would be the main repository' and 'carry' the results with them to all medical encounters*." (Final Office Action, pages 5-6.)

Quite clearly the Affidavit discloses a broadband ("Internet-based"), secure repository for the "accurate" storage of patients' medical record data. Thus, and at least from the Examiner's review, the Affidavit is wholly sufficient to swear behind Snowden.

IV. Argument with Respect to Group IV Claim (claim 20)

Claim 20 Should Be Declared Allowed.

In neither the non-final nor the final Office Action did the Examiner ever review certain claims. For example, there is no disclosure in any of the cited references relating to claim 20 with regard to the element: "accuracy and correctness of said at least one medical record is better than exists at the source site from which the medical record was obtained." None of the cited references, and none of the Examiner's comments, discloses or suggests a computer-

networked system where the medical records are *more* accurate than the records collected from the source sites where the records originated.

Nevertheless, in the final Office Action, the Examiner states that this element of claim 20 can be found in col. 1, lines 29-37 and col. 4, line 60 to col. 5, line 11 of Sheppard. Appellant has reviewed these passages of Sheppard and can find no such disclosure or anything related to the noted aspect of claim 20. The information contained within Shepard's source medical records *cannot* be better than exists at the source from which the record was obtained. This is at least because the hospital, physician or health care worker is the source of the record. In other words, the Shepard system only envisions creating original medical records at the source. Therefore, Shepard cannot logically be a system of creating medical record that are "better" than exist at the source from which the records were originally obtained (*i.e.,* better than the original record). Consequently, claim 20 should immediately be declared allowable.

Conclusion

Appellant respectfully submits that the present application is in condition for allowance, which action is courteously requested. Please charge any shortage in fees due in connection with the filing of this paper to **Deposit Account No. 14-1437 referencing Attorney Docket No. 8123.003.US**. Please credit any excess fees to such account.

Respectfully submitted,
NOVAK DRUCE & QUIGG LLP

Date: October 30, 2006

By: _____
James Remenick
Registration No. 36,902

Customer No. 28694
Novak, Druce & Quigg LLP
1300 Eye Street, N.W.
400 East Tower
Washington, DC 20005
Telephone: (202) 659-0100
Facsimile: (202) 659-0105

CLAIMS APPENDIX

Claim 1. (previously presented) A broad-band, computer-based networked system comprising:

a collection of patient-based electronic medical records of a plurality of persons, at least one of which is encrypted or secured when collected, accessed, inputted, viewed, integrated or transmitted, wherein:

the medical records are obtained and electronically compiled from a plurality of sources;

one or more medical records of the collection possess a characteristic of non-repudiation such that medical information contained within said medical records is verified as to accuracy and certified for accuracy;

the medical record of a person is transmitted in whole or in part only to that person and others authorized by that person;

each medical record is supplemented with additional information; and

additional medical records for additional persons are added to the collection;

a secure access for allowing each person to access only their own medical record; and

at least another secure access for allowing said others authorized to access only that person's medical record.

Claim 2. (original) The system of claim 1, wherein said medical records are electronically complied by direct input or digital scanning of written information into a computer-readable format.

Claim 3. (original) The system of claim 1, wherein the sources are selected from the group consisting of hospitals, clinics, physician's offices, pharmacies and combinations thereof.

Claim 4. (original) The system of claim 1, wherein said medical records are transmissible through the Internet.

Claim 5. (original) The system of claim 1, wherein the medical record for each person contains one or more of: a table of contents, an index, a source notation for information

contained within the medical record, an electronic search tool, annotations for errors, linked annotations for errors, treatment options, health care choices, verification standards and news items relevant to the information in the medical record.

Claim 6. (original) The system of claim 1, wherein the secure access and the another secure access comprise passwords or encryption keys.

Claim 7. (original) The system of claim 1, wherein the others authorized are selected from the group consisting of physicians, nurses, hospitals and health care institutions.

Claim 8. (previously presented) The system of claim 1, wherein all of the medical records of the collection possess the characteristic of non-repudiation.

Claim 9. (previously presented) The system of claim 1, wherein said non-repudiated medical record is primary for treatment of the patient to whom said non-repudiated medical record pertains.

Claim 10. (previously presented) The system of claim 1, wherein the medical information of each medical record of said one or more non-repudiated medical records is primary for treatment and thereby relied upon by medical care providers in furnishing treatment, by employees in choosing from employer benefit options, and by payors in allocating payment for services.

Claim 11. (previously presented) The system of claim 1, wherein the medical information of each certified medical record is certified by the patient, by the source from which said each medical record was obtained, by a system provider or by a combination thereof.

Claim 12. (original) The system of claim 1, wherein the collection comprises medical records of more than 100,000 persons.

Claim 13. (original) The system of claim 1, wherein said collection complies with a federal or state standard of privacy and security.

Claim 14. (original) The system of claim 13, wherein the federal standard is the Health Insurance Portability and Accountability Act of 1996.

Claim 15. (previously presented) The system of claim 13, wherein said collection complies with all standards of privacy and security for the geographical area in which the system operates.

Claim 16. (original) The system of claim 1, further comprising a fee which is assessed for each access to a medical record.

Claim 17. (original) The system of claim 1, further comprising a fee which is assessed for maintenance of a medical record.

Claim 18. (original) The system of claim 1, wherein each medical record is vetted.

Claim 19. (previously presented) The system of claim 18, wherein the medical information of the vetted medical record contains one or more of: corrections of incorrect information, notations of incorrect information, notations of anomalies, linking of errors, linking of anomalies, notation of discrepancies, linking of discrepancies, and combinations thereof.

Claim 20. (previously presented) A broad-band, computer-based networked system for individual control and management of electronic medical records comprising a plurality of medical records representing a plurality of persons, wherein the medical information of at least one medical record of the plurality has been vetted, such that the medical information of said at least one medical record is better than exists at a source site from which the medical record was obtained and thereby is not subject to repudiation.

Claim 21. (previously presented) The system of claim 20, wherein the medical information of said at least one medical record is certified as to accuracy of transcription.

Claim 22. (original) The system of claim 21, wherein certification represents a predetermined degree of completeness, accuracy or both to said medical records.

Claim 23. (previously presented) The system of claim 20, wherein the medical information of said medical records is further certified as correct.

Claim 24. (original) The system of claim 23, wherein vetted medical records have been reviewed and corrected or annotated for errors, discrepancies and anomalies.

Claim 25. (previously presented) The system of claim 23, wherein the medical information of the vetted medical records contain one or more of: corrections of incorrect information, notations of incorrect information, notations of anomalies, linking of errors, linking of anomalies, notation of discrepancies, linking of discrepancies, and combinations thereof.

Claim 26. (previously presented) The system of claim 20, wherein non-repudiated medical records are primary for treatment of the person to whom each medical record pertains by all health care providers.

Claim 27. (previously presented) The system of claim 20, wherein the plurality of medical records complies with the Health Insurance Portability and Accountability Act of 1996.

Claim 28. (previously presented) The system of claim 27, which further complies with a state standard of privacy and security.

Claim 29. (original) The system of claim 20, wherein access to any one medical record is restricted to the person to whom said one medical record pertains or to others designated and authorized by said person.

Claims 30-45. (canceled).

Claim 46. (previously presented) A computer system for management of patient-based medical records that contain medical information and are not subject to repudiation comprising a database of medical records pertaining to one or more subjects; a receiver for receiving the medical information pertaining to said medical records from one or more senders; a process for

verifying that the medical information received is accurate and correct by at least vetting said medical information; a process for authorizing said senders and said additional receivers according to a set of rules, wherein said set of rules is designated by said subjects; and a transmitter for transmitting at least a portion of said medical records to one or more additional receivers and certifying that the portion transmitted is accurate.

Claim 47. (original) The computer system of claim 46, wherein said database is a secure database.

Claim 48. (original) The computer system of claim 47, wherein said secure database complies with a federal standard of privacy and security.

Claim 49. (original) The computer system of claim 48, wherein the federal standard is the Health Insurance Portability and Accountability Act of 1996.

Claim 50. (original) The computer system of claim 48, which further complies with a state standard of privacy and security.

Claim 51. (previously presented) The computer system of claim 46, wherein said receiver is selected from the group consisting of: modem, cellular receiver, infrared receiver, Ethernet card, facsimile, cable modem, satellite receiver, optical, analog receiver, Internet hub, and web-server.

Claim 52. (previously presented) The computer system of claim 46, wherein said transmitter is selected from the group consisting of: modem, cellular transmitter, infrared transmitter, Ethernet card, facsimile, cable modem, satellite transmitter, analog transmitter, Internet hub, and web-server.

Claim 53. (previously presented) The computer system of claim 46, wherein said process of authorizing comprises public key encryption, digital signatures, biometrics, certificate authorities, or user passwords.

Claim 54. (previously presented) The computer system of claim 46, wherein the process of verifying results in an improved accuracy or correctness of at least a portion of the medical information received from said one or more senders.

Claim 55. (previously presented) The computer system of claim 46, wherein said non-repudiated medical records of said one or more subjects are primary for treatment of said one or more subjects by health care providers not involved with creating said medical information.

Claim 56. (previously presented) The computer system of claim 46, further comprising an integrator for reception, display, analysis and modification of said medical records available to be performed on a plurality of systems of health care providers, payors, clearinghouses, or oversight agencies.

Claim 57. (original) The computer system of claim 46, wherein said database is administered by a service provider other than said subjects, senders, and receivers.

Claim 58. (previously presented) The computer system of claim 46, further including vetting that allows said subjects to supplement said medical records with information relating to the accuracy of said medical records.

Claim 59. (previously presented) The computer system of claim 46, wherein said medical records are owned and controlled by said subjects.

Claim 60. (previously presented) The system of claim 1, wherein the collection is encrypted and secured.

Claim 61. (previously presented) The system of claim 1, wherein the medical information contained within said medical records is verified as accurate and correct by a rules-based process.

Claim 62. (previously presented) The system of claim 61, wherein the rules-based process is computerized in whole or in part and involves screening by medical record paraprofessionals, nurses, physicians or specialist physicians.

Claim 63. (previously presented) The system of claim 1, wherein the medical information contained within said one or more non repudiated medical records is further certified as correct.

Claim 64. (previously presented) The system of claim 1, wherein the medical information of each medical record can be relied upon for all aspects of treatment of the person to whom said each medical record pertains.

Claim 65. (previously presented) A networked system comprising:

a collection of patient-based electronic medical records containing medical information, wherein:

the medical records are obtained and electronically compiled from a plurality of sources;

the medical information contained within one or more medical records is verified as to accuracy and certified as to accuracy, and thereby possesses the characteristic of non-repudiation;

the medical records are transmitted in an encrypted fashion in whole or in part only to that person and others authorized by that person;

each medical record is supplemented with additional information; and

additional medical records for additional persons are added to the collection; and

a capability of having multiple secure accesses for a person and others authorized by the person to access only their own medical record.

Claim 66. (previously presented) The system of claim 65, wherein the medical information contained within said medical records is verified as accurate and correct by a rules-based process.

Claim 67. (previously presented) The system of claim 66, wherein the rules-based process is computerized in whole or in part and involves screening by medical record paraprofessionals, nurses, physicians or specialist physicians.

Claim 68. (previously presented) The system of claim 65, wherein the medical information of the one or more certified medical records has a predetermined degree of completeness, accuracy or both.

Claim 69. (previously presented) The system of claim 65, wherein each medical record can be relied upon for treatment of the person to whom said each medical record pertains.

Claim 70. (previously presented) The system of claim 65, wherein the medical information of all of the medical records of the collection possess the characteristic of non-repudiation.

Claim 71. (previously presented) The system of claim 70, wherein said non-repudiated medical record is primary for all aspects of treatment of the patient to whom said non-repudiated medical record pertains.

Claim 72. (previously presented) The system of claim 65, wherein the medical information of each medical record is further certified as correct.

Claim 73. (previously presented) The system of claim 65, wherein each certified medical record is certified as accurate by the patient, by the source from which said each medical record was obtained, by a system provider or by a combination thereof.

Claim 74. (previously presented) The system of claim 65, wherein each medical record is vetted.

Claim 75. (previously presented) The system of claim 74, wherein the medical information of the vetted medical record contains one or more of: corrections of incorrect information,

notations of incorrect information, notations of anomalies, linking of errors, linking of anomalies, notation of discrepancies, linking of discrepancies, and combinations thereof.

EVIDENCE APPENDIX

Copies of the Rule 131 Affidavits submitted on August 26, 2005 are attached hereto.

PATENT
New Attorney Docket No. 144009.00200
Old Attorney Docket No. 031672.0005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Wm.A. Knaus & R.D. Marks	)
		) Group Art Unit: 3626
U.S. Appl. No.:	09/822,261	)
		) Examiner: Lena Najarian
Filing Date:	April 2, 2001	)

Title: BROADBAND COMPUTER-BASED NETWORKED SYSTEMS FOR CONTROL AND MANAGEMENT OF MEDICAL RECORDS

MAIL STOP - AMENDMENT

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

DECLARATION UNDER 37 C.F.R. §1.131

We, William A. Knaus with a residence address at 1929 Lewis Mountain Road, Charlottesville, VA 22903, and Richard D. Marks with a residence at 6004 Balsam Drive, McLean, VA 22101, are co-inventors of the invention disclosed and claimed in the above-captioned patent application.

Prior to December 6, 1999, we conceived and reduced to practice the systems and methods according to the claims of the instant patent application, at least to the extent that such systems and methods are disclosed in U.S. Patent Application No. 09/908,524 (Snowden), U.S. Provisional Application No. 60/169,065 (the Snowden Provisional), U.S. Patent Application No. 09/776,673 (Malik), and U.S. Provisional Application No. 60/60/200,091 (the Malik Provisional) (collectively the "Cited References"). Accordingly, Snowden, Malik, the Snowden Provisional and the Malik Provisional cannot be considered to be prior art to our claimed invention.

In support of this Declaration, attached hereto is a document that was prepared by us prior to December 6, 1999 ("Exhibit A"). As clearly established by this document, we conceived and reduced to practice the systems and methods according to the claims of the instant patent application, at least to the extent that such systems and methods are disclosed in the Cited References.

Please note that Exhibit A is being provided here in redacted form. The material redacted contains personal information of a select few people who received this document in confidence. Although the redactions are not proprietary, we do not wish to place personal information into the public record. If the Examiner would like to review the entire document, we would be pleased to allow the Examiner to review an unredacted copy at a personal interview.

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above identified application or any patent issued thereon.

_____ Date: August ___, 2005

Name: William A. Knaus

Date: August 23, 2005

Name: Richard D. Marks

Attached: Exhibit A

PATENT
New Attorney Docket No. 144009.00200
Old Attorney Docket No. 031672.0005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Wm.A. Knaus & R.D. Marks	)
		) Group Art Unit: 3626
U.S. Appl. No.:	09/822,261	)
		) Examiner: Lena Najarian
Filing Date:	April 2, 2001	)

Title: BROADBAND COMPUTER-BASED NETWORKED SYSTEMS FOR CONTROL AND MANAGEMENT OF MEDICAL RECORDS

MAIL STOP - AMENDMENT

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

DECLARATION UNDER 37 C.F.R. §1.131

We, William A. Knaus with a residence address at 1929 Lewis Mountain Road, Charlottesville, VA 22903, and Richard D. Marks with a residence at 6004 Balsam Drive, McLean, VA 22101, are co-inventors of the invention disclosed and claimed in the above-captioned patent application.

Prior to December 6, 1999, we conceived and reduced to practice the systems and methods according to the claims of the instant patent application, at least to the extent that such systems and methods are disclosed in U.S. Patent Application No. 09/908,524 (Snowden), U.S. Provisional Application No. 60/169,065 (the Snowden Provisional), U.S. Patent Application No. 09/776,673 (Malik), and U.S. Provisional Application No. 60/60/200,091 (the Malik Provisional) (collectively the "Cited References"). Accordingly, Snowden, Malik, the Snowden Provisional and the Malik Provisional cannot be considered to be prior art to our claimed invention.

In support of this Declaration, attached hereto is a document that was prepared by us prior to December 6, 1999 ("Exhibit A"). As clearly established by this document, we conceived and reduced to practice the systems and methods according to the claims of the instant patent application, at least to the extent that such systems and methods are disclosed in the Cited References.

Please note that Exhibit A is being provided here in redacted form. The material redacted contains personal information of a select few people who received this document in confidence. Although the redactions are not proprietary, we do not wish to place personal information into the public record. If the Examiner would like to review the entire document, we would be pleased to allow the Examiner to review an unredacted copy at a personal interview.

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above identified application or any patent issued thereon.

William G. Knaus Date: August 25, 2005

Name: William A. Knaus

_____ Date: August ___, 2005

Name: Richard D. Marks

Attached: Exhibit A

EXHIBIT A

"MANAGING THE INFORMATION SO YOU AND YOUR DOCTOR CAN MANAGE THE CARE"

Redacted

Redacted

Redacted

THE STRATEGIC AIM

Create a new "trusted agent" for a consumer focused, clinician sanctioned, Internet based healthcare information, decision support, and treatment recommendation utility.

THE BUSINESS OPPORTUNITY

Enable consumers to use the Internet as their "preferred first stop" for obtaining all non-emergency medical care advice and guidance. Prior to visiting a clinician or a clinic, the person would transmit their medical data and problem or inquiry to the "trusted agent" via the Web. The trusted agent would search a variety of objective and valid sources to obtain comprehensive state of the art individualized medical information, prognoses, and a comprehensive assessment of treatment alternatives and likely outcomes. The structure of this information would enable individual consumers to interpret the findings and then interact with clinicians and health care delivery systems as informed consumers and prudent purchasers of specific services. The nature and efficieney of the patient-clinician contact would be improved by concentrating communication on the patient's values and preferences for specific alternatives. Considerations of cost, convenience, and quality (practitioner performance, reputation, etc.) could also have a larger role in treatment choices

SPECIFIC OBJECTIVES AND CORE COMPETANCES

1.Develop and disseminate new conceptual and technical approaches to;

a) The structure and organization of medical data and information content,

b) the process of information search and inquiry response

c) the presentation and graphical user interface for healthcare data

2. Continually evaluate the usefulness and impact of these approaches on the quality of healthcare delivery with the results supporting improvements in content and presentation.

BRIEF BACKGROUND AND RATIONALE

It is widely acknowledged that the Internet will change the way we think about and the way we conduct many aspects of our economy and our society. The most immediate and profound changes have been in commerce where the marketing and purchase of a wide variety of goods and services are being transferred to the Internet. Overtime, it is envisioned that more and more services will have a part of their market in Internet space. The Internet is also about information and control. As Andrew Shapiro writes in his book, The Control Revolution, the Internet will reduce and in some cases eliminate intermediaries by bringing consumer and supplier in direct contact with identical information. As a heavily information based service industry healthcare will also be affected and changed by the Internet but there are some unique considerations.

Historical and Ongoing Obstacles to IT in Healthcare

While medical care is an information based service industry, it is very far behind other service sectors in its use of information technology. Much of this resistance, in my experience, comes from the conservative nature of the profession and it's practitioners. During this century medicine has largely functioned as a cottage industry with the medical practitioner as the gatekeeper for medical information, treatment recommendations, and provision of services. Approaches to health care information technology have been slow because practitioners and systems have demanded individual customized approaches to data acquisition, handling and transfer and have actively resisted standardization because it threatens their control. Healthcare IT companies have attempted to overcome this resistance by developing proprietary enterprise wide solutions that can never be truly enterprise wide because of the lack of standards and the non-integrated nature of most "integrated" health care systems. There is no industry giant in healthcare IT with the market divided among 12 or so primary proprietary enterprise type systems (Cerner, HBOC, Eclipsys, SMS, etc.) and hundreds if not thousands of "best of breed" isolated management or decision support systems)HCIA, Medical Logic, MeCon, APACHE, etc.) The government has never used its large market presence to promote either integration or standardization. Current financial incentives do not directly reward investment or use of IT services.

The result is substantial inefficiency in the storage, retrieval, and availability of data. The consequences are a large number of medical mistakes, great variations in the choices of therapies and an increasing lack of trust in the ability of the profession to manage and make appropriate use of ongoing scientific discoveries.

A New Model-The Consumer as integrator and "standard bearer"for healthcare data

My approach would use the power of the Internet to develop a new model for healthcare information dissemination and interpretation. Rather than attempting to convince clinicians to adopt state of the art information retrieval or decision support systems or for health care systems to coordinate thousands of disparate islands of data, the individual patient would be the main repository their medical information, would be able to initially access its clinical implications, and then "carry" the results with them to all medical encounters regardless of location. This would effectively eliminate the

intermediary, the " IT poor practitioner or the IT dysfunctional health system" as the repository of healthcare data and knowledge. In effect, the medical care system would need have "read only"information systems. They would be capable of receiving individual patient data and recommendations and then updating it with current data at the end of the encounter and then return it to the patient.

The simple but powerful rationale behind this effort is that all healthcare transactions are centered on patients or patient data. They are the most efficient way to integrate the system. The patient, members of their family, or trusted advocates are also the most interested in insuring that their medical information be accurate and the advice given appropriate. Because of the focused nature of their problem they also will be able to devote the time to research the implications of their findings. The incentives for them are more control over healthcare decision and greater assurance of quality care, two highly desired outcomes for individuals.

Individuals therefore would be the main customers for this service. The revenue model could be a yearly or monthly subscription based or pay as you go service akin to Internet access or cable use. This approach to revenue would also insure that the "trusted agent" would remain an unbiased and independent provider of objective data that would be in the patient's best interest.

Because most services would still be provided through the practitioner, the information and data provided by the trusted agent would have to respected and acknowledged by the clinician. Appropriate incentives and respect would need to be created in order for this to occur. I admit this is the least well worked out part of this proposal.

THE UNDERLYING ASSUMPTIONS I AM MAKING (In no particular order)

1.The Internet will become the primary source of information for both the clinician and the consumer
2.There are currently no trusted agent brokers for clinician or patient specific electronic health care information or queries.
3.Medical therapy is going to become more and more individualized
4.Medical services will be more consumer driven
5.The amount of information available when considering a medical decision is going to grow.
6.The demands of privacy (and the draft HIPPA regulations) will increasingly stress data transfer security and encourage "ownership" and dissemination of this detailed medical data to the individual.
7.Cost and convenience concerns will make the location of care more flexible and price, convenience, and brand name or provider reputation more important

HOW THIS IS DIFFERENT

As the mad scramble for health care portals continue, there is a notable lack of content-development. More importantly, there is an explicit assumption that the practitioner is the disseminator of all recommendations or interpretation and that 'systems" not individuals will control the data. Even the most prestigious and well-regarded emerging Internet sites provide generic or expert based ("ask a doc") advice oriented around condition or problem not individual. As the above assumptions indicate I am proposing that this approach is wrong. Healthcare will change and healthcare data and recommendations will become much more "retail"-- accessible to all, not just practitioners and institutions- and that the provision of medical services (as opposed to information) will increasingly become a commodity.

HOW THIS WOULD WORK-PROSTATE CANCER AS AN EXAMPLE

A man is recently diagnosed with prostate cancer. He has the results from his physical and laboratory tests. He goes to the "trusted agent" and structures a free text inquiry about his prognosis and treatment alternatives. The tool searches the medical literature, finds either the necessary applicable data or, if available, the algorithms that permit the clinician to take a patient's medical data, age, family history, PSA level, Gleason Score (if a biopsy was done) and provide a very detailed estimation of prognosis under the three dominant treatment options; surgery, radiation therapy, and watchful waiting.

Initially this web based approach might program these algorithms into the instrument to enable the individual to have this data so they would understand their situation and what options were available and appropriate. Overtime, as Bill Detmer, has taught me, the inquires would not have to rely on pre-programmed algorithims but could be more flexible with inquiries addressed from raw data. The presentation would be done both with a combination of specifically designed and tested web-based graphic and textual patient education material that would enable the person to drill down into the specifics of the data and the recommendations. They could obtain additional details on what surgical options means in terms of description of the procedure. They could investigate how their personal preferences and values might influence the decision to have surgery.

I can also envision linking such data to specific medical resources requested by the patient i.e. the local urologist for data on the number of surgeries he had performed and his outcomes. Soon, as Andrew Heller has indicated, when broadband is used, the system could be even more interactive. It could monitor and direct care services directly from the patient's home-say monitoring the daily volume and nature or urinary flow and functional status with the presumption that the preferred site of most care and virtually all of patient-physician communication in the future will be the patient's home or office.

NEXT STEPS

1. Reaction to the overall concept and willingness to remain in the dialogue (anyone can drop out with no hard feelings)

2. Discussion of the concept of "trusted agent" as an operating business concept
My thinking here is that the managed care companies were supposed to do this but they really blew any chance by focusing on short term profits without much investment In information technology or quality of consumer services. The current backlash against managed care, however, and the non-physician gatekeeper provides an excellent opportunity to position this new entity. The slogan might be something like "Managing Information so that you and your doctor can Manage the Care"

3, Are there 2 separate but related business here i.e. a personal medical data management company and a medical information and recommendation entity?

4. What do we do about the docs? While I do not believe they are our main customer they must be satisfied and accepting of the data and information otherwise they could sabotage the effort.

5.How to get started- Given all the talent and resources briefly outlined above there are a lot of potential options. If we get through this initial conceptual phase, I will be glad to outline them with your help.

That's it.

RELATED PROCEEDINGS APPENDIX

None.